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VIA ECF

April 25, 2023

Honorable Julien Xavier Neals
United States District Court
Martin Luther King Federal Building
50 Walnut Street
Newark, NJ 07101

Re: *Ralica Zamfirova et al. v. AMAG Pharmaceuticals, Inc.*
Civil Action Number 2:20-cv-00152-JXN-JBC
Letter Regarding Plaintiff's Notice of Supplemental Authority

Dear Judge Neals:

Defendant AMAG Pharmaceuticals, Inc. ("AMAG") respectfully submits this letter in response to Plaintiffs' April 21, 2023 Notice of Supplemental Authority attaching a copy of the United States Food and Drug Administration's (FDA) recent Final Decision in the formal proceedings to withdraw Makena from the market. [ECF No. 100].

As Your Honor is aware, this is a consumer class action in which Plaintiffs challenge AMAG's marketing of the prescription drug Makena, a progestin treatment indicated to reduce the risk of preterm birth, as effective for its FDA-approved indication. Plaintiffs contend that, contrary to the FDA's determination when it approved the drug in 2011, Makena is not effective to reduce the risk of preterm birth, based on the results of a clinical trial entitled "Progestin's Role in Optimizing Neonatal Gestation" ("PROLONG"), released in March 2019. As a result, Plaintiffs allege that certain statements that Makena is effective on AMAG's website and in a patient education brochure were misleading under several state consumer protection laws.

On August 23, 2021, AMAG filed a motion to dismiss Plaintiffs' Second Amended Complaint, arguing that:

(1) Plaintiffs' claims are preempted by federal law [ECF No. 79-1 at 20-35];

(2) Plaintiffs' claims should be dismissed or stayed under the doctrine of primary jurisdiction [*id.* at 35-38];

(3) Certain of Plaintiffs' state-law consumer protection claims are barred by safe harbors [*id.* at 38-42];

(4) The learned intermediary doctrine bars Plaintiffs' claims [*id.* at 43-44];

(5) Plaintiffs fail to plead their fraud-based claims with particularity [*id.* at 45-48];

(6) Plaintiffs fail to adequately plead their consumer protection claims [*id.* at 49-66]; and

(7) Plaintiffs lack standing to assert their RICO claim and fail to meet applicable pleading standards with respect to that claim [*id.* at 67-75].

In light of the FDA's Final Decision, AMAG hereby withdraws its argument that the case should be dismissed or stayed under the doctrine of primary jurisdiction. [ECF No. 79-1 at 35-38]. That argument was based in large part on the fact that the FDA was holding formal administrative proceedings regarding the proposed withdrawal of Makena from the market, which are now concluded. AMAG disagrees with the FDA's Final Decision, but acknowledges that, now that the drug has been withdrawn from the market, there is no longer a risk that inconsistent adjudications could negatively impact patient access to an approved medication.

To be clear, however, AMAG is ***not*** withdrawing its other arguments for dismissal, and the FDA's Final Decision does ***not*** undermine those arguments, including AMAG's argument that Plaintiffs' claims are preempted by federal law. As the Court previously explained, the marketing statements Plaintiffs challenge were entirely consistent with Makena's FDA-approved labeling at all times the drug was on the market, and AMAG was prohibited by federal law from marketing the drug in a manner inconsistent with its labeling. [ECF No. 62 at 7-9]. Plaintiffs have argued that AMAG could have unilaterally changed its labeling under the FDA's "Changes Being Effected" (CBE) regulation, and then changed its marketing accordingly. [ECF No. 87 at 8-11]. AMAG contends that the CBE regulation does not allow a unilateral labeling change of the type Plaintiffs contend was required by state law here – essentially removing Makena's only approved indication from the label in its entirety. [ECF No. 79-1 at 23-25; ECF No. 88 at 12-16]. But even if it did, Plaintiffs have not plausibly alleged that the CBE was available in this situation.

Specifically, Plaintiffs' claims based on purchases of Makena prior to the release of the PROLONG results in March 2019 are preempted because Plaintiffs have not plausibly alleged the existence of "newly acquired information" prior to that time that would have allowed AMAG to change Makena's labeling without prior FDA approval. [ECF No. 62 at 15-16; ECF No. 79-1 at 26-31; ECF No. 88 at 4-8]. Plaintiffs' claims based on purchases after the release of the PROLONG results are preempted because the FDA formally rejected a proposed label change AMAG had submitted to disclose the results of the PROLONG study, thereby providing "clear evidence" that the FDA would not have accepted the label change Plaintiffs' contend was required by state law. [ECF No. 79-1 at 32-35; ECF No. 88 at 9-12]. That the FDA

has now chosen to withdraw Makena's approval provides further "clear evidence" that it would not have accepted the proposed labeling change Plaintiffs contend was required.

Respectfully submitted,

s/David R. Kott

David R. Kott

DRK/nrm

cc: All Counsel of Record (via ECF)